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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/542,983
Filing Date: July 21, 2005
Appellant(s): ZERBE ET AL.

Eric B. Meyertons
Reg. No. 34,876
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on 23 September 2009 appealing from the Office action mailed on 23 December 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The examiner agrees with the characterization of the claims in the brief; however, it is noted that claim 1 is the only claim being appealed, as it is the only claim under active prosecution.

(4) Status of Amendments After Final

The appellants' statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellants' statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,946,685	EDGREN	9-1988

(9) Grounds of Rejection

The following ground of rejection is applicable to the appealed claim:

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,946,685 ("Edgren").

Edgren discloses a multilayer oral dosage form comprising:

- the matrix core comprising a therapeutically effective amount of a first drug wherein the matrix core allows sustained release of the first drug of instant claim 1(a) (*see* col. 6, line 55 – col. 7, line 54; figure 3, 13 and 14);
- the first layer in contact with the core comprising a therapeutically effective amount of a second drug wherein the first layer allows sustained release of the first drug of instant claim 1(b) (*see* col. 6, line 55 – col. 7, line 54; figure 3, 12 and 14); and
- the second layer in contact with the core comprising a therapeutically effective amount of a second drug wherein the second layer allows immediate release of the second drug of instant claim 1(c) (*see* col. 6, line 55 – col. 7, line 54; figure 3, 15 and 16).

(10) Response to Argument

(a) Appellants argue, "[i]n order to anticipate Appellant's claims, lamina 12 and lamina 13 would need to both be sustained release layers. Applicant submits that laminate layer 13, however, does not allow "sustained release of the first drug." Instead laminate layer 13 of Edgren appears to be an instant release layer." See brief, page 4, last full paragraph.

Examiner respectfully submits that the Edgren reference explicitly teaches both lamina 12 and lamina 13 as a sustained release formulation.

At the outset, it is noted that Edgren teaches that a higher molecular weight cellulose ether, for example having a molecular weight of 241,000, maintains mechanical integrity longer than a lower molecular weight cellulose ether, for example having a molecular weight of 27,800 (see col. 11, lines 6-12). As such, examiner respectfully submits that a formulation comprising higher molecular weight cellulose ether will inherently result in a sustained release pharmacokinetic profile.

Lamina 12 is disclosed as comprising up to 80 wt. % hydroxypropylmethylcellulose (see col. 5, line 18) while lamina 13 is disclosed as comprising up to 60 wt. % hydroxypropylmethylcellulose (see col. 5, line 23). As such, both lamina 12 and lamina 13 are disclosed as containing a very high concentration of cellulose. Lamina 12 and lamina 13 are disclosed as having a hydroxypropylmethylcellulose comprising the same degree of polymerization range, i.e. 40 to 1600 (see col. 6, lines 44 and 47) and the same viscosity range, i.e. 2 to 225,000 (see col. 6, lines 44 and 48). Finally, both lamina 12 and lamina 13 are disclosed as comprising high molecular weight hydroxypropylmethylcellulose, i.e. 307,200 (see col. 6, lines 45 and 48). As such, at least in the embodiment disclosed in col. 6, lines 39-54 of Edgren, both lamina 12 and lamina 13 may be formulated as sustained release compositions.

This is confirmed in example 25, where both the first lamina and the second lamina contain high molecular weight hydroxypropylmethylcellulose, i.e., 242,000 MW.

The drug release curve corresponding to the formulation of example 25, i.e. at figure 11, shows a smooth sustained release trajectory without an immediate release burst, evincing that both laminae of the formulation were sustained release compositions.

In view of the above embodiments, examiner respectfully submits that the Edgren reference discloses both lamina 12 and lamina 13 as sustained release compositions.

(b) Appellants quote two passages from the Edgren reference (see page 5, first paragraph, and paragraph bridging pages 5 and 6) to support the argument that Edgren, "...appears to teach an oral dosage form that includes a layer that provides instant release, a layer that provides prolonged release, and a coating that provides instant release of a drug." See brief, page 5, second paragraph.

The appellants' arguments are based on what the examiner believes to be a narrow interpretation of the prior art. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). See MPEP § 2111 and 2123. As explained above, the embodiment disclosed at col. 6, lines 39-54, example 25, and figure 11 of Edgren all disclose a formulation that is comprised of a first lamina sustained release composition and a second lamina sustained release composition.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Hasan S. Ahmed

/Hasan S Ahmed/

Examiner, TC 1600

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